



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[Docket No. CDC-2021-0001]**

**Final Revised Vaccine Information Materials**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Under the National Childhood Vaccine Injury Act (NCVIA), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all healthcare providers are required to give to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) prior to administration of specific vaccines. On January 11, 2021, CDC published a notice in the *Federal Register* (86 FR 1977) seeking public comments on proposed updated vaccine information materials for vaccines covered by the National Vaccine Injury Compensation Program. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. By March 31, 2022,

all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization.

**DATES:** No later than March 31, 2022, each healthcare provider who administers a vaccine covered by the National Vaccine Injury Compensation Program to any child or adult in the United States shall discontinue use of previous editions and provide copies of the updated vaccine information materials referenced in this notice, in conformance with the CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021, prior to administering such vaccinations.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Johnson-DeLeon, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop: H 24-6, 1600 Clifton Road, N.E., Atlanta, Georgia 30329. Telephone: (404) 639-8817.

**SUPPLEMENTARY INFORMATION:** The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services (the Secretary) to develop and disseminate vaccine

information materials for distribution by all healthcare providers in the United States to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements, have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate healthcare provider and parent organizations, and the Food and Drug Administration. Section 2126 also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine;
- (2) A concise description of the risks associated with the vaccine;
- (3) A statement of the availability of the National Vaccine Injury Compensation Program; and

(4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any healthcare provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: <https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html>.

#### **Revised Vaccine Information Materials**

The revised vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and

Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials pertaining to vaccines covered under the National Vaccine Injury Compensation Program have been finalized and are available to download from

<https://www.cdc.gov/vaccines/hcp/vis/index.html> or

<http://www.regulations.gov> (see Docket Number CDC-2021-0001). The revised Vaccine Information Statements are the following:

"DTaP (Diphtheria, Tetanus, and Pertussis) Vaccine: What You Need to Know," publication date August 6, 2021.

"Hepatitis A Vaccine: What You Need to Know," publication date October 15, 2021.

"Hepatitis B Vaccine: What You Need to Know," publication date October 15, 2021.

"*Haemophilus influenzae* type b (Hib) Vaccine: What You Need to Know," publication date August 6, 2021.

"HPV (Human Papillomavirus) Vaccine: What You Need to Know," publication date August 6, 2021.

"Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know," publication date August 6, 2021.

"Influenza (Flu) Vaccine (Inactivated or Recombinant): What You Need to Know," publication date August 6, 2021.

"MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know," publication date August 6, 2021.

"MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know," publication date August 6, 2021.

"Meningococcal ACWY Vaccine: What You Need to Know," publication date August 6, 2021.

"Meningococcal B Vaccine: What You Need to Know," publication date August 6, 2021.

"Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know," publication date August 6, 2021.

"Polio Vaccine: What You Need to Know," publication date August 6, 2021.

"Rotavirus Vaccine: What You Need to Know," publication date October 15, 2021.

"Tdap (Tetanus, Diphtheria, and Pertussis) Vaccine: What You Need to Know," publication date August 6, 2021.

"Td (Tetanus and Diphtheria) Vaccine: What You Need to Know," publication date August 6, 2021.

"Varicella (Chickenpox) Vaccine: What You Need to Know," publication date August 6, 2021.

"Your Child's First Vaccines: What You Need to Know," publication date October 15, 2021.

With publication of this notice, by March 31, 2022, all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization in conformance with CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021.

Dated: December 20, 2021.

**Angela K. Oliver,**

*Executive Secretary,*

*Centers for Disease Control and Prevention.*

[FR Doc. 2021-27929 Filed: 12/23/2021 8:45 am; Publication Date: 12/27/2021]